

# EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
SOUTHERN DIVISION**

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GENUS LIFESCIENCES, INC.,

Plaintiff,

v.

U.S. FOOD AND DRUG  
ADMINISTRATION, et al.,

Defendants

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Case No. 8:20-cv-3282-PX

**DECLARATION OF MAUREEN CAVANAUGH  
IN SUPPORT OF LANNETT’S MOTION TO INTERVENE**

I, Maureen Cavanaugh, declare as follows:

**I. Personal Background**

1. I am currently Senior Vice-President and Chief Commercial Operations Officer at Lannett Company, Inc. (“Lannett”). I have held that position since May 2018. In my current role with Lannett, I lead the commercial team, including sales and marketing, research and development, business development, and regulatory affairs for Lannett’s brand-name and generic pharmaceutical products. Prior to joining Lannett, over the course of more than 11 years, I held multiple pharmaceutical development, sales, and marketing positions at a major pharmaceutical company.

2. I have either personal knowledge or knowledge obtained in the course of my duties at Lannett as to the facts averred to in this Declaration. I would testify to these facts if called to testify in this matter. I submit this declaration in support of Lannett's motion to intervene in the above-captioned matter.

## **II. Lanett has Significant Legally Protected Interests in This Matter**

3. On November 23, 2016, U.S. Food and Drug Administration ("FDA") received a New Drug Application ("NDA") from Genus for a cocaine hydrochloride nasal solution drug product named Goprelto. On September 21, 2017, Lannett submitted NDA number 209575 to FDA for the same drug product under the name Numbrino. FDA then conducted a review of Lannett's NDA and determined that the application was sufficiently complete to permit a substantive review and filed Lannett's NDA 60 days after the date the FDA received the application. On July 20, 2018, FDA issued a Complete Response Letter ("CRL") to Lannett. In response to that CRL, on June 21, 2019, Lannett submitted additional data to the FDA in support of its Numbrino NDA. On December 14, 2017, the FDA approved Genus's Goprelto NDA. Subsequently, on January 10, 2020, the FDA approved Lannett's NDA for Numbrino.

4. Numbrino's NDA was originally submitted by Cody Laboratories, a wholly-owned subsidiary of Lannett. At the time, Cody Laboratories was based in Cody, Wyoming. Once requisite stability data and all other supportive data had been obtained from another Lannett facility, located in Carmel, New York, and after the FDA granted approval of Lannett's NDA, Lannett informed FDA of its intention to change manufacturing locations, and Lannett submitted the required data by way of a "Changes Being Effected" procedure.

5. Lannett has spent considerable research effort and financial resources in developing the drug product and obtaining FDA approval to market the product. The unexpected withdrawal of a drug approval can have devastating effects to the business of a drug manufacturer such as Lannett.

### **III. Genus's Demands in its Complaint Threaten to Impair Lannett's Interests**

#### **A. Loss of Lannett's NDA**

6. If Genus successfully receives declaratory and injunctive relief as sought in its Complaint in this matter, Lannett may lose its NDA approval for Numbrino. Additionally, Lannett may be forced to wait until Genus's New Chemical Entity Exclusivity ("NCEE") expires on December 14, 2022, to file a new NDA or ANDA at that time. The harm that would be caused to Lannett if it were prevented from marketing Numbrino would be substantial.

7. Delayed marketing of Lannett's Numbrino would not only harm Lannett, but would also harm patients and government-funded and private healthcare programs who would be required to pay higher costs of a Genus monopoly on this drug product. Consumers would be deprived of the benefit of competition in the market for this drug product.

#### **B. The Risks to Lannett's Exclusivity Rights for Numbrino**

8. If Genus's demand for relief is granted in full, Lannett ultimately may be deprived of its period of being the sole alternative pharmaceutically equivalent drug product. When a drug product is marketed as the sole alternative version, that product can be expected to quickly gain market share as it competes in the marketplace based upon quality, availability, customer service and price. Conversely, when multiple alternative or generic products enter the market at the same

time, the market share for any one such drug product is much smaller, and the price for that product is generally much lower. As a result, companies like Lannett invest heavily in an effort to be the sole alternative equivalent version of a drug product. Genus's requested Court judgment in this matter could eliminate Lannett's competitive advantage for Numbrino as the sole approved alternative for this drug.

I declare under penalty of perjury that the foregoing is true and correct. Executed on December <sup>14</sup>\_\_\_\_, 2020.

Hatboro, PA

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City, State of Signature

DocuSigned by:

*Maureen Cavanaugh*

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Maureen Cavanaugh  
SVP, Chief of Commercial Operations  
Lannett Company, Incorporated